3. 510(k) Summary

JUN 2 8 2010

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K100322

1. Submitter's Identification:

TaiDoc Technology Corporation
6F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

Correspondence:
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Regulatory Affairs Specialist
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Date of preparation: February 1, 2010

2. Device name:
Proprietary name: TD-4277 BLOOD GLUCOSE MONITORING SYSTEM MODEL TD-4277
Regulatory information:
   A. Regulation section: 21 CFR § 862.1345, Glucose Test System
      21CFR 862.1660 Quality control material (assayed and unassayed).
   B. Classification: Class II (Glucose Test System)
      Class I (Quality control material (assayed and unassayed) (reserved)
   C. Product Code: NBW, System, Test, Blood Glucose, Over The Counter
      LFR, glucose dehydrogenase, glucose

JJX Single (Specified) Analyte Controls (Assayed and Unassayed)

Panel: 75, Clinical Chemistry – Glucose Test System

3. Intended Use:

TD-4277 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Professionals may use the test strips to test capillary and venous blood samples, but lay user may not test venous blood samples

4. Device Description:

The kit of TD-4277 BLOOD GLUCOSE MONITORING SYSTEM MODEL TD-4277 consists of: the meter with blood glucose measurement function, test strips and control solutions. These products have been designed and tested to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:

A. Predicate device name:

TaiDoc Pro I Glucose Test Strip, k082169

FORA G30 blood glucose monitoring system, k090187

B. Comparison with predicate:

The TD-4277 BLOOD GLUCOSE MONITORING SYSTEM MODEL TD-4277 has the equivalent technological characteristics and the similar intended use as the predicate devices.

6. Test Principle:

For blood glucose, the detection and measurement is by an electrochemical biosensor technology using glucose dehydrogenase.

7. Performance Characteristics:

The laboratory and clinical studies for the performance of TD-4277 BLOOD

GLUCOSE MONITORING SYSTEM MODEL TD-4277 demonstrated that the performance of this system meets its intended use.

8. Conclusion:

   Based on the information provided in this submission, the TD-4277 BLOOD GLUCOSE MONITORING SYSTEM MODEL TD-4277 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Taidoc Technology Corporation
c/o Debra Liang
Regulatory Affairs Specialist
6f, No. 127, Wugong 2nd Rd, Wugu Township
Taipei County, 248
TW - CHINA (TAIWAN)

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 28 2010

Re: k100322
Trade/Device Name: TD-4277 Blood Glucose Monitoring System, Model 4277
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: June 25, 2010
Received: June 28, 2010

Dear: Ms. Liang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment G.

Indications for Use

510(k) Number: K100322

Device Name: TD-4277 BLOOD GLUCOSE MONITORING SYSTEM, MODEL TD-4277

Indications for Use:

TD-4277 Blood Glucose Monitoring System, Model TD-4277 is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Professionals may use the test strips to test capillary and venous blood samples, but lay user may not test venous blood samples.

Prescription Use __X___ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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